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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,745	03/18/2004	Tuan Q. Tran	07860004US	5337

7590 12/01/2006
McGuire Woods LLP
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EXAMINER

PATEL, NIHIR B

ART UNIT PAPER NUMBER

3772

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/802,745	Applicant(s) TRAN ET AL.	
	Examiner Nihir Patel	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09.13.2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12 and 15-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12 and 15-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on September 13th, 2006 have been fully considered but they are not persuasive. The applicant argues that Harris does not disclose a drug delivery mouthpiece that is structured and arranged such that a patient's breathing generates airflow that follows the airflow path defined by the hollow body and the baffle to deliver a medicament to the patient. The examiner disagrees with the applicant's arguments. Harris does disclose a drug delivery mouthpiece that is structured and arranged such that a patient's breathing generates airflow (**see column 9 lines 5-10**) that follows the airflow path defined by the hollow body (**see figure 2**) and the baffle **89** (**see figure 2**) to deliver a medicament to the patient.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims **12, 15, 16 and 19** are rejected under 35 U.S.C. 102(b) as being anticipated by Harris et al. (US 3,861,386).

4. As to **claim 12**, Harris teaches a nebulizer that comprises a hollow body (**see figure 2; the interior of tube 77 is defined as the hollow body**) having a top and bottom; an intake port **117** (**see figure 2**) and delivery port **140** (**see figure 2**) proximate the top of the hollow body; a reversibly attachable connection port proximate the bottom of the hollow body (**see figures 2 and 6; the cap 26 is defined as a reversibly attachable connection port**); a nebulizer inlet and

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a nebulizer outlet proximate the bottom of the hollow body (**see figure 2 the air flow 142 indicates that the nebulizer inlet and nebulizer outlet are below the delivery port 140 which can be defined as proximate the bottom of the hollow body**); and a baffle 89 (**see figure 2**) at least partially disposed within the hollow body, such that the baffle is a barrier and wherein the hollow body and the baffle define an air flow path having portions parallel to one another through an interior of the hollow body (**see figure 2; as shown in figure 2 the airflow 142 is parallel**); and wherein the drug delivery mouthpiece is structured and arranged such that a patient's breathing generates airflow (**see column 10 lines 5-10**) that follows the airflow path defined by the hollow body (**see figure 2**) and the baffle 89 (**see figure 2**) to deliver a medicament to the patient.

5. **As to claim 15**, Harris teaches an apparatus wherein the baffle 89 includes a substantially planar member disposed between the intake flow path and the delivery flow path (**see figure 2**).

6. **As to claim 16**, Harris teaches an apparatus wherein the connection port is configured to reversibly attach to a chamber (**see figure 2; the cap 26 is defined as a connecting port and is reversibly attached to a chamber by screws 62 as shown in figure 2**).

7. **As to claim 19**, Harris teaches an apparatus wherein the delivery port 140 is disposed on a conduit attached proximate a top of the hollow body (**see figure 2**).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims **17 and 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris et al. (US 3,861,386) in view of Lester (US 4,333,450).

11. **As to claims 17 and 18**, Harris substantially discloses the invention as claimed, see rejection of claim 12 above, but does not disclose a baffle that is configured to protrude into a chamber connected to the connection port. Lester discloses a nebulizer manifold that does provide a baffle **9 (see figure 2)** that is configured to protrude into a chamber **50** connected to the connection port. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Harris's invention by providing a baffle that is configured to protrude into a chamber connected to the connection port as taught by Lester in order to collect the large water drops.

12. Claims **20-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris et al. (US 3,861,386) in view of Blacker (US 6,929,003).

13. **As to claims 20-22**, Harris substantially discloses the invention as claimed, see rejection of claim 12 above, but does not disclose an exhaust outlet that is sealable and includes a one-way valve. Blacker discloses a nebulizer apparatus and method that does provide an exhaust outlet

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that is sealable and includes a one-way valve (see column 8 lines 35-45). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Harris's invention by providing an exhaust outlet that is sealable and includes a one-way valve as taught by Blacker in order to direct exhalation away from the nebulizer.

Remarks

14. The examiner acknowledges the cancellation of claims 1-11, 13, 14 and 23.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Nihir Patel


11/27/06